UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES *ex rel.* [UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendants.	Case No: **FIRST AMENDED COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT [31 U.S.C. §§ 3729 *et seq.*]** **JURY TRIAL DEMANDED** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* Doe,

Plaintiffs,

v.

GENOMIC HEALTH, INC., AGENDIA INC., BIODESIX, INC., CARIS LIFE SCIENCES, BIOCEPT, INC., GUARDANT HEALTH, FOUNDATION MEDICINE, INC., THE MEDICAL FOUNDATION, AMERIPATH, ACL LABORATORIES, UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER, CLEVELAND CLINIC, COMMUNITY HEALTH NETWORK, ASPIRUS RIVERVIEW HOSPITAL, FRANCISCAN HEALTH, CLINTON MEMORIAL HOSPITAL REGIONAL CANCER CENTER, KISHWAUKEE HOSPITAL, AURORA RESEARCH INSTITUTE, AURORA HEALTH CARE, INC. AND AFFILIATES, SILVER CROSS HOSPITAL, ALEXIAN BROTHERS MEDICAL CENTER, INDIANA UNIVERSITY HEALTH, INC., INDIANA UNIVERSITY HEALTH BALL MEMORIAL HOSPITAL, THEDACARE REGIONAL MEDICAL CENTER, ELKHART GENERAL HOSPITAL, ADVOCATE HEALTH CARE NETWORK AND SUBSIDIARIES, ADVOCATE BROMENN MEDICAL CENTER, OSF SAINT FRANCIS MEDICAL CENTER, PALOS COMMUNITY HOSPITAL, MOSES H. CONE MEMORIAL HOSPITAL OPERATING CORPORATION D/B/A CONE HEALTH, UC HEALTH, UNIVERSITY OF PITTSBURGH MEDICAL CENTER D/B/A UPMC, and UNIVERSITY OF ROCHESTER MEDICAL CENTER

Defendants.

Case No: 17-CV-4460

FIRST AMENDED COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT [31 U.S.C. §§ 3729 *et seq.*]

JURY TRIAL DEMANDED

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

Qui tam Plaintiff-Relator Doe ("Relator"), on behalf of the United States of America for this Complaint against Genomic Health, Inc., Agendia Inc., Biodesix, Inc., Caris Life Sciences, Biocept, Inc., Guardant Health, Foundation Medicine, Inc. (the "Defendant Diagnostic Laboratories"); the Medical Foundation, AmeriPath, ACL Laboratories (the "Defendant Pathology Laboratories") (collectively the "Defendant Laboratories"); University Hospitals Cleveland Medical Center, Cleveland Clinic, Community Health Network, Aspirus Riverview Hospital, Franciscan Health, Clinton Memorial Hospital Regional Cancer Center, Kishwaukee Hospital, Aurora Research Institute, Aurora Health Care Inc. and Affiliates, Silver Cross Hospital, Alexian Brothers Medical Center, Indiana University Health Inc., Indiana University Health Ball Memorial Hospital, ThedaCare Regional Medical Center, Elkhart General Hospital, Advocate Health Care Network and Subsidiaries, Advocate BroMenn Health Center, OSF Saint Francis Medical Center, Palos Community Hospital, Moses H. Cone Memorial Hospital Operating Corporation d/b/a Cone Health, UC Health, University of Pittsburgh Medical Center d/b/a UPMC, and University of Rochester Medical Center (the "Defendant Hospitals"), collectively "Defendants," alleges as follows:

I. INTRODUCTION AND OVERVIEW

1. This complaint concerns a coordinated effort by Defendants to delay orders of potentially life-saving tests for the sole purpose of obtaining Medicare reimbursement to which they are not entitled. As detailed below, Defendants are engaging in ongoing violations of Medicare's "14-day rule," under which Medicare will not separately reimburse for molecular diagnostic tests on specimens collected during a beneficiary's inpatient hospital stay when the test is ordered within 14 days of the beneficiary's discharge from the hospital.

2. Defendant Diagnostic Laboratories offer a variety of molecular diagnostic tests designed to provide information on a number of cancer-related genes that can help guide a patient's treatment. The tests, which are a subset of clinical diagnostic laboratory tests, can provide patients and physicians with clinically valuable, highly sophisticated information about the type of cancer a patient has and the likelihood of response to a specific treatment approach. Patients who undergo these tests may have very serious medical conditions and would benefit greatly from prompt testing.

3. In most cases, Medicare will not pay separately for clinical laboratory tests ordered within 14 days of a patient's hospital discharge. In these circumstances, tests are considered part of the hospital services provided during the patient's stay and thus not eligible for payment beyond what Medicare reimburses the hospital for services while the patient is hospitalized. In contrast, diagnostic tests that are ordered more than 14 days after an inpatient's discharge from the hospital are generally separately reimbursed to clinical laboratories by Medicare Part B, based on an established fee schedule.

4. In the instant case, the Defendant Hospitals conspire with the Defendant Laboratories to knowingly and systematically delay orders for clinical laboratory tests until 14 days after hospital inpatients are discharged so that Medicare Part B pays separately for those tests. The delayed ordering is undertaken without regard for patient health and in violation of the federal False Claims Act, 31 U.S.C. §§ 3729, *et seq*. The Defendants thus knowingly cause Medicare Part B to reimburse the Defendant Laboratories for molecular diagnostic tests that do not qualify for separate Medicare Part B reimbursement.

5. *Qui tam* Plaintiff-Relator Doe seeks through this action to recover all available damages, civil penalties, and other relief for the FCA violations alleged in this Complaint.

II. PARTIES

A. The Relator

6. Plaintiff-Relator Doe is a resident of Wisconsin and has deep expertise in diagnostic laboratory and anatomic pathology services. Doe has knowledge of the Medicare billing practices of the Defendants in this *qui tam* action.

B. Defendants

7. Defendant Genomic Health, Inc. ("Genomic") provides genomic-based diagnostic tests used to help guide cancer treatment. Its headquarters are in Redwood City, California. Genomic Health offers the Oncotype DX tests to help physicians determine the best course of treatment for breast (21-gene test), prostate (17-gene test), and colon cancers (12-gene test). It conducts business and has representatives nationwide, and has centralized billing and ordering systems.

8. Defendant Agendia Inc. ("Agendia") provides molecular diagnostic tests for cancer patients. Its headquarters are in Irvine, California, and Amsterdam, the Netherlands. Agendia offers a Mammaprint 70-gene breast cancer recurrence assay and a Blueprint 80-gene molecular subtyping assay. It conducts business and has representatives nationwide, and has centralized billing and ordering systems.

9. Defendant Biodesix, Inc. makes blood-based molecular diagnostic cancer tests to inform treatment decisions based on a patient's specific molecular profile. Its headquarters are in Boulder, Colorado. It offers the Biodesix Lung Reflex tests, including GeneStrat and VeriStrat. It conducts business nationwide and has centralized billing and ordering systems.

10. Defendant Caris Life Sciences ("Caris") creates molecular diagnostic tests to identify molecular targets for cancer treatment. Its headquarters are in Irving, Texas. Caris

offers the Caris Molecular Intelligence test, which examines a patient's molecular makeup to help guide physician treatment, as well as the ADAPT Biotargeting System. It conducts business and has representatives nationwide, and has centralized billing and ordering systems.

11. Defendant Biocept, Inc. ("Biocept"), based in San Diego, California, develops molecular oncology diagnostic tests, specializing in circulating tumor cell and biomarker analysis. Biocept offers blood tests intended to help patients and physicians treat breast and lung cancer. It conducts business nationwide and has centralized billing and ordering systems.

12. Defendant Foundation Medicine offers a variety of molecular genomic profiling tests, including FoundationOne, FoundationOne Heme, and FoundationACT. Its headquarters are in Cambridge, Massachusetts. It conducts business and has representatives nationwide, and has centralized billing and ordering systems.

13. Defendant The Medical Foundation is a clinical laboratory in South Bend, Indiana. It provides pathology services for a variety of hospitals and physicians in Indiana, Michigan, Ohio, and Illinois, including Elkhart General Hospital in South Bend, Indiana. It has centralized billing and ordering systems.

14. Defendant AmeriPath is a laboratory services company that performs a variety of pathology tests. Among other clients, it provides pathology services to Community Health Network Hospitals and Franciscan Health Hospitals in Indiana. It conducts business and has representatives nationwide, and has centralized billing and ordering systems.

15. Defendant ACL Laboratories is a community-based testing laboratory network that is jointly operated by Aurora Health Care, Inc. and Advocate Health Care Network. According to its website, ACL Laboratories provides pathology laboratory testing services to 27 hospitals and performs 24 million laboratory tests each year. It conducts business and has

representatives throughout Wisconsin and Illinois, and has centralized billing and ordering systems.

16. Defendant University Hospitals Cleveland Medical Center ("UH Cleveland Medical Center") is an academic medical center in Cleveland, Ohio and is affiliated with Case Western Reserve University School of Medicine. UH Cleveland Medical Center receives Medicare reimbursements under the Inpatient Prospective Payment System ("IPPS").

17. Defendant Cleveland Clinic is a non-profit academic medical center in Cleveland, Ohio that is owned and operated by the Cleveland Clinic Foundation. Cleveland Clinic receives Medicare reimbursements under the IPPS.

18. Defendant Community Health Network operates a network of hospitals in Indiana. Community Health Network receives Medicare reimbursements under the IPPS.

19. Defendant Aspirus Riverview Hospital is a hospital in Wisconsin Rapids, Wisconsin. It receives Medicare reimbursements under the IPPS.

20. Defendant Franciscan Health is a network of healthcare facilities in Indiana and Illinois. Franciscan Health receives Medicare reimbursements under the IPPS.

21. Defendant Clinton Memorial Hospital Regional Cancer Center ("Clinton Memorial") in Wilmington, Ohio is a member of the James Cancer Network and is affiliated with the Ohio State University Comprehensive Cancer Center. It is owned by RegionalCare Hospital Partners, Inc., a Delaware corporation. Clinton Memorial receives Medicare reimbursements under the IPPS.

22. Defendant Kishwaukee Hospital in DeKalb, Illinois is a private, not-for-profit, short-term, general acute community hospital. It is one health facility of the KishHealth System

and is a member of Northwestern Medicine. It receives Medicare reimbursements under the IPPS.

23. Defendant Aurora Research Institute is a clinical research facility in Milwaukee, Wisconsin. It is part of the Aurora Health Care, Inc. network in Wisconsin. It receives Medicare reimbursements under the IPPS.

24. Defendant Aurora Health Care, Inc. is a Wisconsin nonstock, not-for-profit corporation that is the parent corporation of a group of non-profit and for-profit entities that own and operate health care facilities and provide health care services in Wisconsin and Illinois. Its facilities receive Medicare reimbursements under the IPPS.

25. Defendant Silver Cross Hospital is a 296-bed acute care and general hospital in New Lennox, Illinois. It receives Medicare reimbursements under the IPPS.

26. Defendant Alexian Brothers Medical Center, part of AMITA Health, operates hospitals and medical centers throughout Illinois. It has facilities that are reimbursed under the IPPS.

27. Defendant Indiana University Health, Inc. is Indiana's most comprehensive healthcare system. It is a private, non-profit corporation that is incorporated in Indiana. It operates hospitals and other care facilities throughout the state. Its hospitals receive Medicare reimbursements under the IPPS.

28. Defendant Indiana University Health Ball Memorial Hospital is a teaching hospital in Muncie, Indiana. It is part of the Indiana University Health system and receives Medicare reimbursements under the IPPS.

29. Defendant ThedaCare Regional Medical Center is a hospital in Appleton, Wisconsin. It receives Medicare reimbursements under the IPPS.

30. Defendant Elkhart General Hospital, part of the Beacon Health System, is a hospital located in Elkhart, Indiana. It receives Medicare reimbursements under the IPPS.

31. Defendant Advocate Health Care Network is a faith-based, not-for-profit health system based in Downers Grove, Illinois. According to its website, it is the largest health system in Illinois, with more than 450 sites of care, including 12 acute-care hospitals. Its facilities receive Medicare reimbursements under the IPPS.

32. Defendant Advocate BroMenn Medical Center is a 221-bed not-for-profit hospital located in Normal, Illinois that is a member of Defendant Advocate Health Care Network. It receives Medicare reimbursements under the IPPS.

33. Defendant OSF Saint Francis Medical Center is an acute care hospital in Peoria, Illinois that is a member of OSF HealthCare System. It receives Medicare reimbursements under the IPPS.

34. Defendant Palos Community Hospital is a hospital located in Palos Heights, Illinois. It receives Medicare reimbursements under the IPPS.

35. Defendant Moses H. Cone Memorial Hospital Operating Corporation, d/b/a Cone Health ("Cone Health") is a private, non-profit corporation organized under the laws of North Carolina that provides health care services through a network of hospitals and physician offices in central North Carolina. It receives Medicare reimbursements under the IPPS.

36. Defendant UC Health is a private healthcare system whose principal place of business is in Cincinnati, Ohio. It provides care for patients at two hospitals, the University of Cincinnati Medical Center and West Chester Hospital, in addition to a variety of community settings. UC Health receives Medicare reimbursements under the IPPS.

37. Defendant University of Pittsburgh Medical Center, d/b/a UPMC ("UPMC") is a private, non-profit healthcare system with its principal place of business in Pittsburgh, Pennsylvania. UPMC receives Medicare reimbursement under the IPPS.

38. Defendant University of Rochester Medical Center is an academic healthcare system with its principal place of business in Rochester, New York. It receives Medicare reimbursements under the IPPS.

III. JURISDICTION AND VENUE

39. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

40. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732, which authorizes nationwide service of process. Moreover, Defendants can be found in, reside in, or have transacted the business that is the subject matter of this lawsuit in this District.

41. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because Defendants can be found in, reside in, or have transacted the business that is the subject matter of this lawsuit in this District.

42. The public disclosure provision of the federal False Claims Act, 31 U.S.C § 3730(e)(4)(A), does not apply in this instance. The Relator's complaint is not based upon allegations or transactions of fraud that have been publicly disclosed within the meaning of the False Claims Act. Even if the allegations or transactions of fraud had been publicly disclosed, the Relator is an original source of the information within the meaning of the FCA. Relator's information is based upon personal observations, independent of any relevant public disclosure.

To the extent there has been a public disclosure as defined by 31 U.S.C. § 3730(e)(4)(A), Relator's information materially adds to that which has been publicly disclosed.

IV. APPLICABLE LAW

A. The False Claims Act

43. The federal False Claims Act (the "FCA") was originally enacted during the Civil War. After finding that fraud in federal programs was pervasive and that the FCA, which Congress characterized as the primary tool for combating government fraud, was in need of modernization, Congress substantially amended the FCA in 1986 to enhance the ability of the United States Government to recover losses sustained as a result of fraud against it. Congress intended that the 1986 amendments would create incentives for individuals with knowledge of fraud against the Government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf. Congress further substantially amended the FCA in 2009 and 2010 to, among other things, strengthen whistleblowers' ability to bring and maintain actions on the Government's behalf.

44. The FCA prohibits, *inter alia*: (a) knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval; (b) knowingly making or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim; (c) knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government; and (d) conspiring to violate any of these three sections of the FCA. 31 U.S.C. §§ 3729(a)(1)(A)-(C) and

(G). Any person who violates the FCA is liable for a civil penalty of up to $21,916 for each violation, plus three times the amount of the damages sustained by the United States. 31 U.S.C. § 3729(a)(1).

45. For purposes of the FCA, a person "knows" a claim is false if that person: "(i) has actual knowledge of [the falsity of] the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1). The FCA does not require proof that the Defendant specifically intended to commit fraud. *Id.* Unless otherwise indicated, whenever the word "know" and similar words indicating knowledge are used in this Complaint, they mean knowledge as defined in the FCA.

46. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States and to share in any recovery. Such a person is known as a *qui tam* "relator." The FCA requires that the *qui tam* relator's complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

B. The Medicare Program

47. Congress established the Medicare program, or Title XVIII of the Social Security Act, in 1965 with the goal of providing nationalized health coverage for Americans aged 65 and older. In addition to the elderly, a large portion of Medicare's patient population is disabled. In 2015, Medicare covered roughly 55 million Americans, either through the traditional federally-administered Medicare program or through a private health plan, known as a Medicare Advantage plan. Medicare is funded through the Medicare Trust Funds, which rely on employee payroll deductions, beneficiary premiums, and government funds.

48. The United States Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS"), an agency within HHS, direct and manage the Medicare program.

49. Medicare has four parts: Part A, the Basic Plan of Hospital Insurance, which covers the cost of inpatient hospital services; Part B, which provides medical insurance; Part C, which includes managed care plans; and Part D, which provides prescription drug benefits. Medicare Part A reimburses hospitals for medically necessary inpatient hospital services, including laboratory tests provided to an inpatient. Medicare Part B includes reimbursements for covered clinical laboratory tests performed in an outpatient setting when the tests are medically necessary and reasonable.

C. Medicare Coverage of Clinical Laboratory Diagnostic Tests

50. This case arises from Defendants' violation of three different Medicare rules: (1) the rules governing bundling of payment for hospital services; (2) the "date of service" rules governing clinical laboratory tests; and, (3) the "place of service" rules governing laboratory testing. Each is considered in turn below.

a. Bundling of Payment Requirement

51. Medicare bundles payment to hospitals for most inpatient and outpatient care services. The vast majority of hospitals that treat inpatient Medicare beneficiaries are paid under the inpatient prospective payment system ("IPPS"). *See* Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (1983). Payment under the IPPS for inpatient care is made by Part A of Medicare. Under the IPPS, hospitals are not reimbursed based on their actual costs. Rather, Medicare reimburses them in a single, all-inclusive payment based on the Diagnostic Related Group ("DRG") schedule. 42 U.S.C. § 1395ww(d). DRG reimbursements reflect the

average cost that a hospital incurs in treating a patient with a particular diagnosis, adjusted for different geographic areas. Under the IPPS, a Medicare patient's diagnosis is matched to a DRG and reimbursement is then based on the schedule.

52. Clinical laboratory tests provided to inpatients are bundled into the DRG reimbursement. Medicare Claims Processing Manual Ch. 16, § 30.3 ("Payment to a hospital for laboratory tests furnished to an inpatient, whose stay is covered under Part A, is included in the PPS rate for PPS facilities . . . ."). Accordingly, an outside laboratory that provides clinical diagnostic testing services for a hospital inpatient who is a Medicare beneficiary must bill the hospital for its services, and not Medicare. The hospital then pays the laboratory from its DRG payment. 42 U.S.C. § 1395y(a)(14).

53. Payment for services provided to Medicare beneficiaries as outpatients is made by Part B of Medicare. Before 2014, clinical diagnostic laboratory tests provided in hospital outpatient settings were separately reimbursed by Medicare based on rates set in the Clinical Laboratory Fee Schedule ("CLFS"). 78 Fed. Reg. 74,826, 74,939 (Dec. 10, 2013); 42 C.F.R. 419.22(l) (2011). Since 2014, payment for most laboratory tests provided to outpatients has been packaged under the Outpatient Prospective Payment System ("OPPS"). Under the OPPS, Medicare reimbursement to hospitals for outpatient services that are integral, ancillary, supportive, dependent, or adjunctive to the primary services provided in the hospital outpatient setting is bundled into the hospital's Ambulatory Payment Classifications ("APC"). 42 U.S.C. § 1395l(t) (2016); 42 C.F.R. 419.2(b)(17) (2016); 78 Fed. Reg. 74,826, 74,939 (Dec. 10, 2013); Centers for Medicare and Medicaid Services, Medicare Claims Processing Manual, CMS Pub. 100-04, Ch. 16, § 30.3 (Rev. 3685, Dec. 22, 2016); available at http://www.cms.hhs.gov. CMS now only pays separately for laboratory tests for outpatient beneficiaries when: (i) they are the

only services provided to a beneficiary on a claim; (ii) they are "unrelated" laboratory tests, meaning that they are on the same claim as other hospital outpatient services, but are ordered for a different diagnosis than the other hospital outpatient services and are ordered by a different practitioner than the practitioner who ordered the other hospital outpatient services; (iii) they are molecular pathology tests; or (iv) the laboratory tests are considered preventive services. 81 Fed. Reg. 45,604, 45,628 (July 14, 2016). Medicare excludes molecular pathology tests from the bundled payment under the OPPS because "these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we proposed to package." 78 Fed. Reg. 74,826, 74,939 (Dec. 10, 2013). Likewise, CMS excludes laboratory tests designated as "advanced diagnostic laboratory tests" ("ADLTs") from packaging under the OPPS. 81 Fed. Reg. 79,569-79,570 (Nov. 14, 2016). Medicare reimburses both molecular pathology tests and ADLTs provided to Medicare beneficiaries in an outpatient setting based on the CLFS.

54. Medicare considers an "outpatient" to be "a person who has not been admitted by the hospital as an inpatient but [who] is registered on the hospital records as an outpatient and receives services (other than supplies alone) from the hospital or CAH [critical access hospital]." Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual, CMS Pub. 100-02, Ch. 6, § 20.2 (Rev. 82, Feb. 8, 2008); available at http://www.cms.hhs.gov. To be an "inpatient" for Medicare purposes, a patient must be formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner. 42 C.F.R. § 412.3(a) (2016).

55. The bundling of payments is intended to incentivize the efficient delivery of quality, medically necessary services to Medicare beneficiaries and to control program expenditures on hospital services delivered on both an inpatient and outpatient basis. *See* H.R. Rep. No. 98-25, at 132 (1983), 1983 U.S.C.C.A.N. 219, at 351 (legislation creating the IPPS "is intended to reform the financial incentives hospitals face, promoting efficiency in the provision of services by rewarding cost/effective hospital practices."); 81 Fed. Reg. 45,604, 45,613 (July 14, 2016) (describing the OPPS as "an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care").

b. Date of Service Requirement

56. As described above, the CMS rule governing the date of service of clinical diagnostic tests that use stored specimens is also relevant in the instant case because it determines whether a laboratory service is bundled into the DRG and IPPS. In general, the date of service for clinical laboratory tests is the date the specimen was collected. 42 C.F.R. § 414.510(a) (2008). If the specimen is tested more than 30 days after it was collected, it is considered "archived" and the date of service is the date the specimen was retrieved from storage. 42 C.F.R. § 414.510(b)(2)(ii). For specimens stored less than 30 days from the date of collection, the date of service is the date the test was performed, rather than the date of collection, only if all of the following five conditions are met:

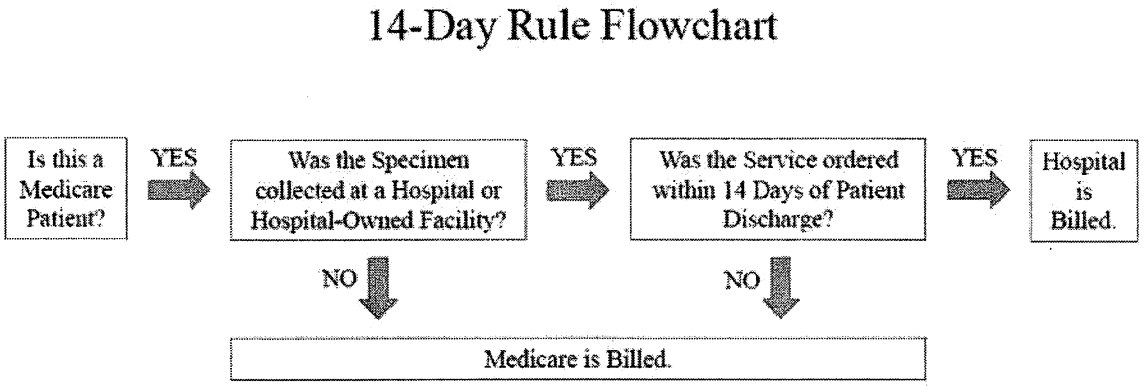
i. The test was ordered by the patient's physician at least 14 days following the date of the patient's discharge;
ii. The specimen was collected while the patient was undergoing a hospital surgical procedure;
iii. It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
iv. The results of the test do not guide treatment provided during the hospital stay; and
v. The test was reasonable and medically necessary for the treatment of an illness.

42 C.F.R. § 414.510(b)(2)(i). CMS has promulgated a rule with virtually identical requirements for chemotherapy sensitivity tests performed on live tissue. 42 C.F.R. § 414.510(b)(3).

57. Therefore, when a test is ordered less than 14 days following the patient's discharge, the date of service remains the date the specimen was collected and the test is bundled into the DRG payment made to the hospital under the IPPS because the date of service fell during an inpatient stay. In contrast, when tests are ordered by the patient's physician 14 days or greater following the patient's discharge from the hospital, they are not necessarily bundled into the DRG, which allows laboratories to bill Medicare Part B for the service if the other requirements of 42 C.F.R. § 414.510(b)(2) are met. *See* 42 C.F.R. § 414.510(b)(2); *see also* Centers for Medicare and Medicaid Services, Demonstrations Manual, Pub. 100-19, Transmittal No. 70, Affordable Care Act – Section 3113 – Laboratory Demonstration for Certain Complex Diagnostic Tests, § 1(A) (March 10, 2011); 71 Fed. Reg. 69,624, 69,706 (Dec. 1, 2006) (noting that the "date of service of a test may affect payment because, if the date of service falls during an inpatient stay or outpatient procedure, payment for the laboratory test usually is bundled with the hospital service."). Medicare reimbursement for clinical laboratory tests under Part B is based on the CLFS. *See* Medicare Claims Processing Manual, Ch. 16, § 20.

58. The 14-day rule preserves bundled payments for services provided during hospital stays, while recognizing that in limited situations, clinical laboratory tests performed on specimens collected while a patient was in the hospital might be legitimately distinguished from the treatment the patient received during his or her hospital stay such that the clinical laboratory tests should be separately reimbursed by Medicare Part B.

59. The following chart illustrates the application of the 14-day rule for clinical diagnostic specimens:



60. Notwithstanding the clarity of the rule, hospitals have a strong financial incentive to delay ordering clinical diagnostic tests until 14 days after their patients have been discharged. The typical charge for a molecular diagnostic test is between $2,500 and $7,200. In certain cases, the charge for a test exceeds $15,000. Medicare reimbursement of molecular diagnostic tests varies widely based on CPT codes and may range from approximately $300 to over $5,000. By delaying ordering by 14 days, hospitals circumvent the requirement that laboratories bill them for tests; instead, the laboratories bill Medicare directly for tests that Medicare would not otherwise separately reimburse. In addition to wrongly billing Medicare, waiting two weeks to order tests on specimens that have already been taken may have profoundly negative consequences for patient care.

61. Likewise, clinical laboratories also have a strong financial incentive to assist hospitals in delaying orders. Hospitals favor clinical laboratories that help them avoid paying for molecular diagnostic tests directly. It is in the clinical laboratories' business interest, therefore, to assist hospitals' circumvention of the 14-day rule.

c. Place of Service Requirement

62. As described above, the CMS rule governing the "place of service" is also relevant in this case. Medicare reimbursement is determined in part by the place the service is undertaken. When an independent clinical laboratory bills Medicare for clinical diagnostic tests, the place of service is the place where the sample was taken. *See* Medicare Claims Processing Manual, Ch. 26, § 10.6. CMS publishes a list of place of service codes to be used on claim forms to specify the type of entity where a service was provided. "If an independent laboratory bills for a test on a sample drawn on an inpatient or outpatient of a hospital, it uses the code for the inpatient (POS code 21), off campus-outpatient hospital (POS code 19), or on campus-outpatient hospital (POS code 22), respectively." *Id.* In contrast, when a laboratory uses a mobile phlebotomist to draw a sample on a Medicare beneficiary, the draw takes place outside of a hospital setting, and thus does not have a hospital-related place of service code. Instead, POS code 15 for mobile unit or code 12 for home is designated.

63. Reimbursement for mobile phlebotomy services designated with POS codes 12 and 15 comes from Medicare Part B and is at a non-facility rate.

64. Certain diagnostic laboratories, including Defendants Biodesix, Biocept, Guardant, and Foundation Medicine conduct molecular diagnostic testing on blood – or so-called "liquid biopsies" – in addition to or in lieu of tissue specimens. The Defendants have a strong financial incentive to use mobile phlebotomists to take blood draws for liquid biopsies on Medicare beneficiaries subject to the 14-day rule. When the sample is drawn outside of a hospital facility, laboratories and hospitals unbundle the blood draw from the DRG reimbursement by changing the place of service. In turn, the molecular pathology labs inappropriately bill Medicare Part B for the test directly. At the same time, the laboratories pay the mobile phlebotomy draw fees – which typically range from $50 to $120 per draw – out of

pocket. The laboratories are willing to absorb this cost because Medicare Part B reimbursements for the tests far exceed the draw fees, making the initial outlay a wise investment.

65. As alleged below, Defendants have defrauded the Medicare program by improperly unbundling payment for clinical laboratory services by fraudulently mischaracterizing the date and/or place of service for molecular diagnostic testing. In doing so, Defendants have recklessly placed the health of Medicare beneficiaries at grave risk.

V. ALLEGATIONS

A. Defendants Conspire to Delay Orders For Molecular Diagnostic Tests Until at Least 14 Days After Patient Discharge

66. Defendant Hospitals, with the knowing assistance of the Defendant Laboratories, intentionally delay orders for molecular diagnostic tests on specimens collected from hospital inpatients until at least 14 days after patient discharge. In this way, Defendant Hospitals avoid paying for diagnostic tests that are properly included in Medicare Part A IPPS reimbursement, and Defendant Diagnostic Laboratories improperly seek separate reimbursement from Medicare Part B for laboratory tests that should be billed directly to the hospitals.

67. The following is a typical chronology of the testing process of laboratories and hospitals that follow the 14-day rule:

a. A tissue specimen is taken or a liquid blood sample is drawn while the patient is being treated at the hospital or within 14 days of discharge;
b. The specimen is sent to the hospital's pathology department or an outside pathology laboratory;
c. The pathology department or outside pathology laboratory sends a report to the treating physician, typically 3-4 days later;
d. Upon reviewing the report, on approximately day 4, the physician decides she wants to order a molecular diagnostic test. To do so, the physician sends a test requisition form to a diagnostic laboratory;
e. The diagnostic laboratory contacts the hospital pathology department or outside pathology laboratory contracted with the hospital to obtain the sample taken from the patient;

f. The pathology department or outside pathology laboratory sends the sample to the diagnostic laboratory;
g. Upon receipt of the sample, the diagnostic laboratory performs the molecular test the physician ordered;
h. The diagnostic laboratory sends the results to the ordering physician;
i. The diagnostic laboratory bills the hospital directly for the test.
j. The hospital submits a claim to CMS for DRG reimbursement that lists the molecular diagnostic test as a service provided in connection with the inpatient stay.

68. In the above chronology, the date of service is the date the specimen was collected, or day zero. The physician ordered the molecular diagnostic test on day four. Because the test was ordered less than 14 days after the patient's discharge from the hospital, Medicare does not provide separate reimbursement for it. Therefore, the laboratory must bill the hospital directly for the test.

69. As described above, hospitals seek to avoid paying for expensive molecular diagnostic tests and often intentionally delay ordering them until well after the patient has been discharged. Hospitals know that if they delay the physician's order for a molecular diagnostic test until 14 days after the patient's discharge, diagnostic laboratories will bill Medicare Part B directly, and will not seek reimbursement from the hospital.

70. The following chronology is an example of how hospitals and laboratories circumvent the 14-day rule:

a. A tissue biopsy is taken or a liquid blood sample is drawn while the patient is at the hospital or within 14 days of his or her discharge;
b. The specimen is sent to the hospital's pathology department or outside pathology laboratory;
c. The pathology department or outside pathology laboratory sends a report to the treating physician, typically 3-4 days later;
d. Upon reviewing the report, on day 4, the physician decides she wants to order a molecular diagnostic test. However, the hospital – typically through its "send out" laboratory – requires that the order be delayed ten additional days before completing a test requisition form (the order) to a diagnostic laboratory;
e. Upon receipt of the test requisition form after day 14, the diagnostic laboratory contacts the hospital pathology department to obtain the patient tissue or blood specimen;

f. The pathology department sends the specimen to the diagnostic laboratory;
g. Upon receipt of the specimen, the diagnostic laboratory performs the molecular diagnostic test the physician ordered;
h. The diagnostic laboratory sends the results to the ordering physician;
i. The laboratory bills Medicare Part B for the test under the CLFS;
j. The hospital does not include the molecular diagnostic test as a service item in its claim to CMS for DRG reimbursement for the inpatient stay.

71. The following is a non-exhaustive list of the molecular diagnostic tests for which Defendants are inappropriately delaying orders and the Current Procedural Terminology ("CPT") codes typically associated with the tests:

72. Defendant Genomic Health, Inc. offers the Oncotype DX RT-PCR tests to treat breast, prostate, and colon cancers. The billing code for the Oncotype DX test is CPT code 81519 (for breast cancer), 81479 (for prostate) and 81525 (for colon cancers).

73. Defendant Agendia offers a Mammaprint 70-gene DNA microarray breast cancer recurrence assay (CPT code 81519) and a Blueprint 80-gene molecular subtyping assay (CPT code 81479).

74. Defendant Biodesix, Inc. offers the Biodesix Lung Reflex tests, including GeneStrat (CPT codes 81235 and 81275) and VeriStrat (CPT code 81538).

75. Defendant Caris Life Sciences offers the Next-Generation Sequencing Cancer Service, which analyzes 46 genes: ABL1 (CPT code 81403); AKT1 (CPT code 81479); ALK (CPT code 88366); APC (CPT code 81202); ATM (CPT code 81408); BRCA1/2 (CPT code 81211); BRAF (CPT code 81210); CDH1 (CPT code 81406); CSF1R (CPT code 81479); CTNNB1 (CPT code 81403); EGFR (CPT code 81235); ERBB2 (CPT code 81479); ERBB4 (CPT code 81479); FBXW7 (CPT code 81479); FGFR1 (CPT code 81405); FGFR2 (CPT code 81404); FLT3 (CPT code 81245); GNA11 (CPT code 81479); GNAQ (CPT code 81403); GNAS (CPT code 81479); HNF1A (CPT code 81405); HRAS (CPT code 81404); IDH1 (CPT code

81403); JAK2 (CPT code 81270); JAK3 (CPT code 81479); KDR (CPT code 81479); KIT (CPT code 81404); KRAS (CPT code 81275); MET (CPT code 81479); MPL (CPT code 81402); NOTCH1 (CPT code 81407); NPM1 (CPT code 81310); NRAS (CPT code 81404); PDGFRA (CPT code 81404); PIK3CA (CPT code 81404); PTEN (CPT code 81321); PTPN11 (CPT code 81406); RB1 (CPT code 81479); RET (CPT code 81406); SMAD4 (CPT code 81406); SMARCB1 (CPT code 81479); SMO (CPT code 81479); STK11 (CPT code 81405); TP53 (CPT code 81405); VHL (CPT code 81404); the Caris Molecular Intelligence test, which tests a variety of markers, including: AR (CPT code 81405); cMET (CPT code 81479); EGFR (CPT code 81235); ER (CPT code 88360); ERCC1 (CPT code 81479); HER2 (CPT code 81479); MGMT (CPT code 81287); MLH1 (CPT codes 81288, 81292, 81293, 81294); MSH2 (CPT codes 81295 - 81297); MSH6 (CPT codes 81298 - 81300); PD-1 (CPT code 88342); PD-L1 (CPT code 88184); Pgp (CPT code 88342); PMS2 (CPT codes 81317-81319); PR (CPT code 88360); PTEN (CPT codes 81321-81323); RRM1 (CPT code 81479); SPARCm (unknown CPT code); SPARCp (unknown CPT code); TLE3 (CPT code 81479); TOP2A (CPT code 81479); TOP01 (unknown CPT code); TS (unknown CPT code); TUBB3 (CPT code 81479); 1p19q# - CPT code 88364-88365); cMET# - CPT code 88342); HER2# (CPT code 81479); TOP2A# (unknown CPT code); ALK# (CPT code 81479); ROS1# (CPT code 81479); and the ADAPT Biotargeting System (unknown CPT code).

76. Defendant Biocept, Inc. provides liquid biopsy tests using its patented Target Selector platform. The Target Selector platform includes 13 different assays: ALK (CPT code 88377); AR (CPT code 88346); BRAF (CPT code 81210); CTC (CPT codes 86152/86153, 88346x1, 88350x2); EGFR (CPT code 81235); ER (CPT code 88346 or 88350); FGFR1 (CPT

code 88377); HER2 (CPT code 88377); KRAS (CPT code 81275); MET (CPT code 88377); PD-L1 (CPT code 88346 or 88350); RET (CPT code 88377); and ROS1 (CPT code 88377).

77. Defendant Foundation Medicine offers the FoundationOne (Z Code ZB0SF, CPT codes 81201, 81206, 81210, 81211, 81235, 81242, 81245, 81270, 81275, 81292, 81294, 81295, 81297, 81298, 81300, 81310, 81315, 81321, 81323, 81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408, 81479, 81455); FoundationOne Heme (Z Code ZBZZO, CPT codes 81170, 81201, 81206, 81207, 81208, 81209, 81210, 81211, 81218, 81235, 81242, 81245, 81261, 81264, 81270, 81272, 81275, 81292, 81294, 81295, 81297, 81298, 81300, 81310, 81311, 81314, 81315, 81321, 81323, 81342, 81400, 81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408, 81479, 81455); FoundationACT (Z Code ZB3BA, CPT codes 81210, 81211,81235, 81245, 81270, 81275, 81310, 81321, 81403, 81404, 81405, 81406, 81408, 81479); and FoundationFocus CDxBRCA (CPT code 81162).

78. The Defendant Clinical Laboratories, Defendant Pathology Laboratories, and the Defendant Hospitals encourage and/or instruct employees and physicians to circumvent the 14-day rule so that payment for molecular diagnostic tests is improperly shifted from the hospitals to Medicare Part B. Although in most cases specimens are collected from inpatients with the intent to conduct molecular diagnostic tests at the time the patient receives hospital services, the test orders are routinely held and not submitted to the Defendant Diagnostic Laboratories until at least 14 days have elapsed from the date of discharge.

79. Relator is aware of multiple instances in which the Defendant Hospitals circumvented Medicare's 14-day rule by intentionally delaying test orders. For example, in June 2016, an oncologist ("Dr. A") at the Clinton Memorial Hospital Regional Cancer Center ("Clinton Memorial") spoke with a Foundation Medicine account executive for Kentucky and

Ohio about how to "get around" the 14-day rule by waiting at least 14 days after patient discharge to order the FoundationOne test on tissue biopsies and FoundationACT test on liquid biopsies so that Medicare Part B would be billed separately for these services rather than Clinton Memorial.

80. Clinton Memorial and Dr. A also frequently order molecular diagnostic tests from Defendant Guardant Health, particularly the Guardant360 test. Clinton Memorial, Dr. A, and Guardant routinely wait 14 days from inpatients' discharge to complete the test orders so that Medicare Part B, and not the hospital, is billed.

81. Similarly, Franciscan Health Lafayette East (formerly Franciscan St. Elizabeth Health) ("Franciscan Health"), a member of the Franciscan Health network, instructs physicians not to send specimens to Foundation Medicine for molecular testing until 14 days after patient discharge. During a January 20, 2017 pathology symposium conference, Relator spoke with a pathologist, ("Dr. B"), who told her that Franciscan Health was upset that it was billed for FoundationOne testing ordered by a colleague of Dr. B, Dr. C of the Horizon Oncology Center in Lafayette. Dr. C orders these tests for patients with lung cancer, and does not wait 14 days until his patients have been discharged from the hospital – where the biopsies are performed – to do so. Franciscan Health has instructed Dr. C and other physicians not to submit specimens taken from patients treated at Franciscan Health for testing until 14 days after discharge so that molecular pathology laboratories, specifically Foundation Medicine, bill Medicare for those services instead of the hospital.

82. It is also the practice of Indiana University Health Ball Memorial Hospital ("Ball Memorial"), a division of the Indiana University Health System, to delay submitting molecular diagnostic test orders for 14 days after patient discharge so that Medicare Part B – rather than the

hospital – will be billed. For example, by email on August 24, 2016, Allison Spradlin, Team Leader and Clinical Oncology Coordinator of the Precision Genomics Program at Ball Memorial, wrote regarding Foundation Medicine Test Requisition Form ("TRF") 17296 that, consistent with Ball Memorial's usual practice: "We biopsied this patient last week, who's [sic] specimen will be sent out once the Medicare 14 day rule is complete."

83. Likewise, Defendant OSF Saint Francis holds specimens until 14 days following patient discharge to avoid receiving a bill from diagnostic laboratories. In a conversation on March 13, 2017, ("Dr. D"), a physician from Illinois Cancer Care in Peoria, Illinois, told Relator that OSF Saint Francis engages in this practice and that it is not what he wants or what is in the best interest of his patients.

84. To circumvent the 14-day rule, Defendant Cone Health also delays sending out specimens until 14 days after inpatient discharge. Relator received an email from Maureen Cooper, Senior Manager for Clinical Collaborations at Foundation Medicine, describing a workshop Ms. Cooper had attended at a conference of the College of American Pathologists. Ms. Cooper wrote that one of the speakers at the workshop, ("Dr. E"), a pathologist at Cone Health in North Carolina, told the audience that the delay in receiving the results of molecular diagnostic tests is a hardship for his patients, and that Cone Health delays sending test orders to put them "outside the Medicare 14-day rule." Dr. E noted that test results can be delayed up to a month for this reason.

85. Defendants UH Cleveland Medical Center, University of Pittsburgh Medical Center, and the University of Rochester Medical Center likewise delay ordering molecular diagnostic testing, including testing done by BioTheranostics. Relator learned from Matthew Rogers, a former BioTheranostics regional account manager who currently works as a

representative for Publicis Touchpoint Solutions/Merck Oncology, that the UH Cleveland Medical Center waits 14 days after inpatient discharge to order molecular diagnostic tests on specimens collected during the inpatient stay. Mr. Rogers told Relator that this is a common practice among most hospitals he has worked with. In addition to UH Cleveland Medical Center, Mr. Rogers also identified UPMC and the University of Rochester Medical Center as hospitals that delay sending out tests to diagnostic laboratories to circumvent the 14-day rule.

86. In a separate communication, Mr. Rogers confirmed to Relator that hospitals and pathology laboratories continue to wait to send specimens for molecular diagnostic tests, including testing to see if lung cancer patients may benefit from a Merck therapy called Keytruda.

87. Defendant Diagnostic Laboratories actively assist and conspire with the Defendant Hospitals to circumvent the Medicare 14-day rule. It is the practice of Defendant Genomic Health, for example, to wait until 15 days after an inpatient has been discharged to send the hospital a test requisition form. In this way, the 14-day rule is circumvented and the laboratory bills Medicare Part B separately for the test, rather than billing the hospital as required by the rule. The Defendants frequently refer to this intentional delay and circumvention as "management" of the 14-day rule.

88. Agendia, a competitor of Genomic, has used a similar approach to circumvent the 14-day rule. During a January 27, 2017 pancreatic cancer symposium, Relator spoke with Lori Leffler, who was a molecular oncology sales specialist for Agendia from 2011 – 2013. Ms. Leffler told Relator that during the time she worked for Agendia, Agendia would hold specimens at their laboratory until 15 days after the patient had been discharged before performing tests. Agendia billed Medicare Part B for this testing rather than hospitals.

89. Among other hospitals, hospitals within the Community Health Network in Indianapolis, Indiana ("CHN") knowingly delay the ordering of molecular diagnostic tests so that Medicare is improperly billed. Staff at CHN openly express appreciation for Genomic Health's assistance in "managing" the 14-day rule, and have requested that other clinical laboratories, such as Foundation Medicine, also help "manage" the rule by delaying orders so that CHN is not billed directly.

90. As part of the effort to "manage" the 14-day rule, and to ensure that Medicare Part B will be billed rather than the hospital, the Defendant Diagnostic Laboratories often alert hospital staff when orders are received before 14 days have elapsed from patient discharge. For example, on September 23, 2016, Linda DeVito, Genomic Health Regional Oncogenomic Liaison, explained to Relator how Genomic Health calls the ordering physician or designated contact nurse and alerts them when an order for a clinical diagnostic laboratory test is submitted less than 14 days from patient discharge. In such instances, the order is pulled or cancelled, and then reinstated after 14 days have passed. Genomic Health also calls the ordering physicians and nurses once 14 days have elapsed to remind them to order or re-order the test. Ms. DeVito bragged that Genomic Health is "very good at helping hospitals manage this rule."

91. Agendia now engages in the same practice. During a January 28, 2017 Wisconsin oncology hematology conference, Relator spoke with a current Agendia molecular oncology sales specialist, Kristie Raupp. Ms. Raupp told Relator that Agendia's current practice is to return any specimens that hospitals send them if 14 days have not elapsed since the patient was discharged. Agendia instructs the hospitals to resubmit the same specimen for testing once 14 days have elapsed so that Agendia can bill Medicare rather than the hospitals. Ms. Raupp further

informed Relator that most hospitals and physicians now have their own systems to ensure they do not send specimens for testing in a timeframe that would result in the hospital receiving a bill.

92. Like Agendia and Genomic Health, Defendant Caris also had a practice of alerting clients that submitted tests before 14 days following patient discharge and asking them to resubmit specimens later so that Caris could bill Medicare Part B for the testing. Lori Leffler, the former Agendia sales specialist, is now the Sales Director at Caris. During the January 27, 2017 pancreatic cancer symposium, Ms. Leffler told Relator that Caris had recently changed its "messaging" to clients after its compliance department decided they should no longer alert clients to specimens sent before 14 days. Caris now informs its hospital clients that if they send a specimen before 14 days following the patient's discharge, Caris will bill the hospital for the testing. The result is the same, however. Ms. Leffler informed Relator that most hospitals routinely wait until 14 days following patient discharge to send specimens to testing for Caris. As a result, Medicare Part B is improperly billed.

93. Defendant Biodesix also knowingly fails to comply with Medicare's 14-day rule. During a presentation to oncologists and pathologists in the spring of 2016, a national trainer from Defendant Biodesix told the audience that Biodesix bills under the Clinical Laboratory Fee Schedule, and that its molecular diagnostic tests are not bound by Medicare's 14-day rule. In this way, Biodesix circumvents the 14-day rule by falsely characterizing its tests as outpatient, even when they were ordered for inpatients within 14 days of discharge and are subject to Medicare's 14-day rule.

94. The "management" – i.e., circumvention – of the 14-day rule through the coordination by the Defendant Hospitals and the Defendant Diagnostic and Pathology Laboratories is widespread. For example, Alexian Brothers Medical Center ("Alexian

Brothers") routinely delays sending specimens to molecular diagnostic laboratories. A representative of Alexian Brothers' send-out laboratory advised Relator that it is the hospital's practice to hold specimens taken from Medicare beneficiaries until 14 days after discharge. For example, molecular diagnostic tests ordered by a Northwest Oncology physician ("Dr. F") have been delayed because Alexian Brothers intentionally failed to send patient specimens for testing until 14 days after patient discharge.

95. Hospitals also fraudulently forward-date test orders to create the appearance of compliance. For example, Relator is aware that the pathology laboratory at Aspirus Riverview Hospital sends test requisition forms to molecular pathology laboratories for testing before 14 days have elapsed, but that are forward-dated beyond the 14-day window. An Aspirus pathologist was upset that Foundation Medicine has billed the hospital for tests she had forward-dated. The Aspirus Riverview pathology laboratory also forward-dates test requests it sends to Caris, but Caris accepts the falsified date and does not bill the hospital for those tests.

96. Other hospitals engage in similar misconduct. For example, in an October 7, 2016 phone call, the pathology department at Alexian Brothers advised that it would hold a patient specimen until 14 days after the patient's discharge because of the Medicare 14-day rule. In this particular instance, the specimen was to receive molecular diagnostic testing by Foundation Medicine pursuant to Test Requisition Form number 181419. To circumvent the 14-day rule, a new forward-dated test requisition form was prepared for the physician. Foundation Medicine advised Alexian Brothers, however, that it would not send the test request to the hospital's pathology department because Foundation Medicine would not assist Alexian Brothers' efforts to circumvent the 14-day rule.

97. Likewise, it is also the practice of the ThedaCare Health to hold specimens 14 days after patient discharge to avoid having the hospital pay for molecular diagnostic testing. Pathology staff at ThedaCare Health also disclosed to Relator that Defendants Guardant Health and Caris Life Sciences both have a practice of helping ThedaCare Health skirt the Medicare 14-day rule by agreeing to ThedaCare's requests to delay testing the specimens until 14 days after the date of patient discharge.

98. Another pathology laboratory, ACL Laboratories ("ACL"), which serves Aurora Health Care, Inc. and Advocate Health System, also holds patient specimens until 14 days after the patients have been discharged. At that time, ACL sends the samples to Caris for testing. Loris Leffler, the Caris Sales Director, informed Relator of this practice, and told Relator that many of those patients undergo surgical procedures specifically to obtain tissue for molecular testing. In fact, physicians have contacted Ms. Leffler asking for test results, and Ms. Leffler has had to inform them that the specimens are still at the pathology laboratory.

99. Relator has also discussed this practice with Dr. D, the physician from Illinois Cancer Care in Peoria, Illinois. On March 13, 2017, Dr. D told relator that Advocate BroMenn Medical Center, a division of the Advocate Health System, holds specimens until after 14 days following patient discharge to avoid receiving a bill. ACL Laboratories is the pathology laboratory that Advocate BroMenn uses for its specimens. ACL and Advocate BroMenn coordinate with each other to delay sending specimens to Foundation Medicine and other diagnostic laboratories for further testing. Dr. D told relator that these delays often mean he does not receive test results for his patients until one month later, and that this is not what is best for his patients.

100. Laboratories that do not help hospitals "manage" – i.e., circumvent – the Medicare 14-day rule are often retaliated against and threatened with the loss of business. It is Foundation Medicine's practice, for example, to tell hospitals that it complies with the Medicare 14-day rule. As a result, Foundation Medicine representatives have received threats and push-back from hospitals that wish to avoid paying for molecular diagnostic tests.

101. For example, in the fall of 2015, an employee of the pathology department at UH Cleveland Medical Center, Kelly Ferguson, asked Relator why Foundation Medicine could not give UH Cleveland Medical Center "the same deal" that Genomic gave them with respect to circumventing the 14-day rule. In particular, UH Cleveland Medical Center wanted Foundation Medicine to cooperate with it to falsify the dates tests are ordered and bill Medicare Part B rather than the hospital for those services. In addition to pressuring laboratories, Ms. Ferguson, on behalf of UH Cleveland Medical Center, now sends back test requests to the ordering physician when they have been submitted before 14 days following patient discharge and asks physicians to resubmit the same sample after the 14-day window.

102. Other pathology laboratories and hospitals also exert pressure on Foundation Medicine to help them circumvent the 14-day rule. On October 17, 2016, Silver Cross Hospital's laboratory manager, Stacy Shaw-George, voiced concern that Silver Cross had received invoices from Foundation Medicine in compliance with the 14-day rule. Shaw-George threatened that the hospital would not pay Foundation Medicine for the tests. When the Foundation representative explained Medicare's requirement of billing the hospital when specimens are collected in connection with an inpatient service and tests are ordered within 14 days of discharge, Ms. Shaw-George responded by threatening that she would ask physicians at Silver Cross to no longer send specimens to Foundation Medicine.

103. On November 7, 2016, a physician ("Dr. G") from Alpha Med Cancer Center ordered a Foundation Medicine test (TRF 166315) on a specimen taken from a Medicare beneficiary. Initial testing on the specimen had been conducted by Palos Community Hospital's pathology lab ("Palos"). When Palos realized the Foundation test order date was less than 14 days from the patient discharge, Palos contacted Dr. G and requested that he cancel his November 7th order and re-order the test after the 14-day window had elapsed on November 15, 2016. Dr. G complied. Palos also requested that Foundation Medicine recognize the November 15th order date and bill Medicare Part B for the service rather than billing Palos for it. Because Foundation Medicine knew the purpose of the new order date was to circumvent Medicare billing rules, it refused to comply.

104. In response, Palos's Manager of Anatomic Pathology, Linda Coomer, wrote in a December 9, 2016 email to Foundation Medicine: "Palos AP lab will not send the block since Foundation will use the first date and charge Palos since the 14 day rule was not in place." In other words, Palos held a patient's sample hostage and refused to send it for further physician-ordered testing because Palos did not want to pay for the service, as it would be required to under Medicare billing rules. This was not an isolated incident. In fact, Ms. Coomer wrote, "this is becoming a recurring issue with the clinicians and Foundation Medicine."

105. Similarly, in 2016, laboratory personnel at UC Health complained to the Foundation Medicine Account Executive for Kentucky and Ohio, Laura McCammon, that UC Health had received a bill from Foundation Medicine for molecular diagnostic testing on a Medicare beneficiary that was ordered less than 14 days from the beneficiary's discharge. The UC Health laboratory personnel informed Ms. McCammon that UC Health would no longer use Foundation Medicine for testing if there was a possibility that UC Health would be billed for

such testing. Ms. McCammon told the laboratory personnel at UC Health that Foundation Medicine was obligated to follow this CMS rule.

106. In some instances, Foundation Medicine has relented to the hospitals' pressure and billed Medicare Part B for tests instead of the hospitals. It is typically the case that Foundation Medicine helps hospitals and providers circumvent the 14-day rule as long as the hospitals and physicians do not tell Foundation Medicine explicitly that the purpose of their requests is to evade the 14-day rule. With respect to the sample referred to in the prior paragraph, for example, a Foundation Medicine sales support specialist, Emily Morse, wrote in an email to Palos pathology laboratory on November 30, 2016 that:

> Unfortunately, at this point, if the doctor was to cancel the order and send new paperwork, we would not accept a new TRF and would have to bill this case as under the 14-day rule if the lab sent us the sample. The ideal process is that a path lab will communicate with the OP [ordering physician] that they need new paperwork, and then the OP will cancel the order with us and resubmit new paperwork after the appropriate date. If at any time it is relayed to FMI that the reason a case is being cancelled and/or new paperwork is being received is to avoid the 14-day rule, however, we are immediately barred from accepting a newly dated TRF. Sending new paperwork when we are aware of an attempt to circumvent billing to the facility qualifies as Medicare fraud, and as you know FMI takes a very strong stance on this matter.

Although Foundation Medicine will not assist in the circumvention of the 14-day rule when it is certain that this is the purpose of a hospital or provider's request, it will look the other way if providers, hospitals, and pathology laboratories do not tell Foundation Medicine why they need another order form. Moreover, Foundation Medicine actively coaches providers not to reveal the fraudulent intent of their requests and explains that, as long as they do not reveal their improper purpose, Foundation Medicine will assist them to delay orders. This conduct is a paradigmatic example of "deliberate ignorance" or "reckless disregard" within the meaning of the FCA.

107. Foundation Medicine also recklessly disregards or deliberately ignores hospitals', pathology labs' and providers' future-dating of test request forms. For example, University Precision Genomics, part of the Indiana University Health system, forward-dates test request forms it sends to its pathology department to make it appear that a physician ordered the test 14 or more days after a patient's discharge, when in reality the physician decided to order the test within 14 days. Consequently, the pathology laboratory at Indiana University delays sending patient specimens to Foundation Medicine for at least 14 days, so that Foundation Medicine bills Medicare rather than Indiana University. Natalie Brown, a Foundation Medicine account executive, informed Relator of this practice on November 30, 2016. Thus, Foundation Medicine knows that Precision Genomics is falsifying order forms but has not taken any steps to remedy this wrongdoing.

108. Given the pervasive nature of Defendants' practice of circumventing the 14-day rule, hospitals have grown to expect that laboratories will comply with their efforts to evade the 14-day rule, even overriding the treating physicians' wishes. The scheme therefore harms not only the federal fisc and patient care, but also encroaches on the autonomy and clinical judgment of physicians.

109. Delaying molecular testing for financial gain can have serious consequences for Medicare beneficiaries. Indeed, treating physicians have frequently expressed concern about the negative impact that circumvention of the 14-day rule has on patient care. For example, on July 25, 2016, an oncologist ("Dr. H") in DeKalb, Illinois, told Relator that the lab at Kishwaukee Hospital urges physicians to hold off ordering any clinical diagnostic laboratory test until 14 days after patient discharge so that Medicare Part B, rather than the hospital, will be billed. The

oncologist told Relator this was frustrating because it delays diagnostic test results, which are used for patient treatment.

110. Likewise, a hematologist and oncologist at CHN in Indianapolis ("Dr. I"), also expressed concern that CHN holds his patients' specimens up and delays test orders, and that this practice compromises his patients' care.

111. On July 29, 2016, Relator discussed the 14-day rule with a physician ("Dr. J") at the Early Phase Cancer Research Program at Aurora Research Institute in Milwaukee, Wisconsin. Dr. J expressed concern that delaying test orders compromises patient care because the tests help guide doctors' treatment decisions, and delay in treatment can be very harmful. Patients often respond rapidly and favorably to treatments supported by molecular testing results, and delay can undermine patients' potential recovery. Dr. J further noted that circumvention of the 14-day rule has been discussed during oncology meetings at the Aurora Institute. He noted that physicians generally acquiesce to the hospital because they do not want to fight administrators about their practice of delaying orders. He also expressed his belief that the Aurora Institute has taken no action to ensure compliance with the 14-day rule.

112. Likewise, Dr. F, the physician at Northwest Oncology, has also expressed concern that delaying orders of molecular diagnostic tests to "manage" the 14-day rule interferes with patient treatment. In one case, Dr. F inquired about a specimen taken at Alexian Brothers on August 29, 2016 for molecular diagnostic testing by Foundation Medicine. Foundation, however, had still not received the specimen from the hospital by September 12, apparently due to Alexian Brother's intentional delay. The physician was especially concerned about Alexian's delay because he wanted to begin patient treatment quickly.

113. Alexian Brothers has continued its callous practice of not sending specimens from patients, including gravely ill patients, for molecular diagnostic testing until 14 days after patient discharge. On February 9, 2017, Dr. K, an oncologist at Northwest Oncology and Hematology in Elk Grove Village, Illinois, ordered FoundationOne testing for a patient with prostate cancer that had metastasized to the kidney. The patient was treated at Alexian Brothers, where a specimen was collected for testing. Foundation Medicine received the order (TRF209569) and requested the specimen from the pathology laboratory at Alexian Brothers Medical Center, which had performed initial testing on the specimen. Alexian Brothers did not send Foundation Medicine the specimen. Instead, it cancelled the test on February 14, 2017 and a new test on the same specimen was ordered on February 16, 2017, which was 14 days after the patient had been discharged. On February 21, 2017, a staff member from Dr. K's office contacted Foundation Medicine seeking the results of the FoundationOne testing because the patient had a follow-up appointment on February 23 and the physician wanted the test results to help him guide therapy options. Foundation Medicine responded that the results of the testing would not be available by February 23rd because Alexian Brothers had cancelled the initial order.

114. Similarly, on approximately October 20, 2016, a physician at Michiana Hematology Oncology, ("Dr. L"), a private physician practice group, explained to Relator that he had requested a bone marrow biopsy procedure be performed on a hospital inpatient receiving chemotherapy. The biopsy was performed at Elkhart General Hospital in South Bend, Indiana on October 13th, and the pathology services were conducted at The Medical Foundation laboratory in South Bend. Additional comprehensive genomic profiling for acute myeloid leukemia was also requested of Foundation Medicine, but when Foundation Medicine asked that The Medical Foundation ("TMF") send a specimen, TMF refused because the patient was an

inpatient. The TMF representative stated that it would wait until 14 days after the patient's discharge so that Medicare Part B would reimburse for the test. Although TMF was advised that the patient was gravely sick and the test results were ordered to evaluate the patient for a transplant, the laboratory continued to refuse to send the specimen out.

115. Subsequently, further inquiry was made of Diane Enos, the surgical records manager at TMF about the laboratory's policies. Ms. Enos confirmed that it was against policy to order molecular diagnostic tests until 14 days after a patient's hospital discharge. Ms. Enos also stated that Elkhart General Hospital expressed concern about billings and that The Medical Foundation was directed not to send any testing out without the permission of Elkhart General Hospital administrative staff.

116. Separately, Dr. L, the Michiana Hematology Oncology physician referred to above, has also expressed concern that hospitals are delaying sending out specimens. To avoid the delay, Dr. L may start performing bone marrow biopsies in his office instead of in hospitals. While understandable, in-office biopsies to avoid unjustified delays in testing further burden Medicare Part B with costs that should appropriately be covered under the DRG payments in the first instance.

117. Defendant hospitals submit claims for Medicare Part A DRG reimbursement using CMS Form 1450, which is also known as the UB-04. Among other information, hospitals are required to list all service and procedure codes connected to the patient's stay, including codes for laboratory tests. CMS Manual System Pub. 100-04 Medicare Claims Processing, Transmittal 1104 (Nov. 4, 2006) at 78-79 (stating that laboratory services should be included as Revenue Code 030X or 031X). Furthermore, CMS Form 1450 contains the following notices: (1) "The submitter of this form understands that misrepresentation or falsification of essential

information as requested by this form, may serve as the basis for civil monetary penalties and assessment and may upon conviction include fines and/or imprisonment under federal and/or state law(s);" and (2) "Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate *and complete*. That the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts." (emphasis added).

118. The Defendant Hospitals identify other services provided to inpatients on their CMS Form 1450s, but the Hospitals intentionally omit tests that should be included on those claims for DRG reimbursement specifically to deceive Medicare by representing, by omission, that molecular diagnostic tests were not part of the inpatient care provided to the beneficiary. In reliance on the Defendant Hospitals' misrepresentations and omissions, CMS reimburses the Defendant Hospitals on a global, DRG basis for services the government believes are completely and accurately represented on the CMS Form 1450. The Defendant Hospitals thus deceive CMS to believe that no molecular diagnostic tests have been performed in connection with the patient's hospitalization.

119. Defendant Diagnostic Laboratories submit claims for Medicare reimbursement using CMS Form 1500. Section 24(A) of that form includes space for providers to record the date a service was provided. By delaying orders of tests until at least 14 days after a patient has been discharged, the order date appears on Form 1500 as a later date, even though the specimen was collected during the beneficiary's hospital stay and the physicians, in most instances, decided they wanted the tests performed well before 14 days had elapsed.

120. Claims for Medicare reimbursement for molecular diagnostic tests that were knowingly delayed in order to create the false appearance of being ordered at least 14 day after

discharge are false or fraudulent claims. As demonstrated above, specimens are routinely collected from inpatients with the intent to conduct molecular diagnostic tests at the time the patient receives hospital services, and physicians typically decide to order molecular diagnostic tests for their patients within a few days of the specimen being taken. Waiting until 14 days have elapsed to fill out the test requisition form after having already decided to order a given test, or misstating the order date as a future date, misleads CMS to mistakenly believe the decision to order the test was made later than it in fact was.

121. Delaying orders of molecular diagnostic tests is an industry-wide practice among hospitals. Defendant clinical diagnostic laboratories actively assist defendant hospitals in this fraudulent practice.

B. Defendants Use Mobile Phlebotomists to Avoid the Application of the 14-Day Medicare Rule

122. In addition to "managing" the 14-day rule by delaying orders of tests, Defendant Diagnostic Laboratories also skirt the 14-day rule by using mobile phlebotomists to take blood draws on Medicare beneficiaries subject to the rule. Defendants intentionally avoid testing specimens taken during an inpatient stay and instead use mobile phlebotomists to take "liquid biopsies" off-site, but within 14 days of patient discharge. In many if not most cases, the defendants intentionally refer patients for off-site testing within 14 days of discharge in order to unbundle molecular diagnostic tests from IPPS reimbursement and wrongly bill them to Medicare Part B.

123. The following is an example of the chronology of the testing process of hospitals and laboratories that circumvent the 14-day rule through the use of mobile phlebotomy:

a. A patient, often an oncology patient, receives medical treatment on an inpatient basis, and is discharged from the hospital;

b. During the patient's inpatient stay, or within two weeks following the patient's discharge, the patient's physician orders a liquid biopsy for the patient and indicates that mobile phlebotomy is required on a diagnostic laboratory test requisition form;
c. The diagnostic laboratory schedules a blood draw appointment outside of a hospital setting, typically at the patient's home;
d. A phlebotomist employed by or contracted with the diagnostic laboratory conducts the blood draw at a non-hospital setting, typically the patient's home;
e. The mobile phlebotomist sends the blood sample to the diagnostic laboratory for analysis;
f. The diagnostic laboratory bills Medicare Part B for these services.

124. Relator has learned from a former Biocept employee that Biocept and Guardant both use mobile phlebotomists to take blood for liquid biopsies on Medicare beneficiaries otherwise subject to the 14-day rule. In claiming reimbursement from Medicare Part B, Biocept and Guardant indicate a non-hospital "place of service" code on CMS Claim Form 1500. Because the place of service is listed as a non-hospital setting, the 14-day rule does not apply, and Medicare Part B reimburses the tests separately.

125. Although mobile phlebotomy may offer an important service to home-bound or isolated patients, in this instance Defendant Diagnostic Laboratories utilize mobile phlebotomy in order to circumvent Medicare's 14-day rule. In particular, Defendant Diagnostic Laboratories promote their service as a means to circumvent Medicare bundled billing policies and to obtain Medicare Part B reimbursements that otherwise should not be available.

126. In addition to Biocept and Guardant, Defendant Biodesix also uses mobile phlebotomists to circumvent the 14-day rule. On August 4, 2016 Relator spoke with a Biodesix helpline representative regarding a test Relator wanted to send Biodesix for testing. Relator mentioned the patient was a Medicare beneficiary who fell within Medicare 14-day rule and the Biodesix representative told Relator that Biodesix uses mobile phlebotomy to "deal with" that scenario—i.e., to unbundle those services and fraudulently allow laboratories to seek additional

Medicare reimbursement for them. In addition, Foundation Medicine launched a pilot program in 2016 to start using mobile phlebotomy in five of its sales territories across to the country for the same purpose—evading the application of the 14-day rule. Due to the success of the pilot program, Foundation Medicine now offers mobile phlebotomy services nationwide for its FoundationACT and FoundationOne Heme tests.

127. An important reason that Foundation Medicine offers mobile phlebotomy services is to unbundle reimbursement for those services and unlawfully increase the Medicare reimbursements. During a January 30, 2017 Foundation Medicine training, Ali Soufan, a Foundation Medicine Associate Product Manager, told an audience of Foundation Medicine employees:

> Perhaps the most important benefit to utilizing mobile phlebotomy is it has absolutely no association to the 14-day rule at all. And so, although that is something we have to be very careful to promote externally, that is definitely something to keep in mind internally.

These comments make clear that Foundation Medicine knowingly circumvents important Medicare rules.

128. Defendants Biodesix, Biocept, Guardant, and Foundation Medicine act in concert with Defendant Hospitals and physicians to arrange for mobile phlebotomy for Medicare patients. Relator has learned from a physician at the Cleveland Clinic, ("Dr. "M"), that the Cleveland Clinic has contracted with laboratories that use mobile phlebotomists to take blood on their patients outside of the hospital setting so the 14-day rule will not apply to tests ordered on those specimens. The physician further observed that mobile phlebotomists were not necessary for his patients because their blood could easily be drawn while they were receiving treatment at the hospital or clinic.

129. Claims for Medicare Part B reimbursement for molecular diagnostic tests in instances where mobile phlebotomists are used to circumvent the 14-day rule are false or fraudulent claims. In addition, use of mobile phlebotomists to defeat the 14-day rule leads to unnecessary additional encounters and unnecessary delay and segmentation in the provision of care.

130. Like the "management" of the 14-day rule, Defendants' use of mobile phlebotomists to seek Medicare Part B reimbursement to which they are not entitled is an industry-wide, nationwide practice.

VI. CAUSES OF ACTION

Count I
Federal False Claims Act
31 U.S.C. §§ 3729(a)(1)(A), (B), (C) and (G)

131. Relator realleges and incorporates by reference the allegations contained in paragraphs 1-121 above as though fully set forth herein.

132. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended.

133. By and through the acts described above, Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729(a)(1)(A).

134. By and through the acts described above, Defendants have knowingly made or used, false records or statements material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

135. By and through the acts described above, Defendants have knowingly conspired to violate the stated provisions, in violation of 31 U.S.C. § 3729(a)(1)(C).

136. By and through the acts described above, Defendants knowingly concealed or improperly avoided or decreased an obligation to pay or transmit money or property to the Government, in violation of 31 U.S.C. § 3729(a)(1)(G).

137. The Government, unaware of the falsity of all such claims made or caused to be made by Defendant, has paid such false or fraudulent claims that would not have been paid but for Defendants' illegal conduct.

138. By reason of Defendants' acts, the United States has been damaged in a substantial amount to be determined at trial.

139. Additionally, the United States is entitled to the maximum penalty of up to $21,916 for each and every violation alleged herein.

VII. PRAYER

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. §§ 3729, *et seq.*;

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $10,957 and not more than $21,916 for each violation of 31 U.S.C. § 3729;

3. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the Federal False Claims Act;

4. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

5. That the United States and Relator recover such other and further relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: May 11, 2018

Respectfully submitted,

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Certificate of Service

I hereby certify that on this 11th day of May, 2018, a copy of the First Amended complaint was served by certified mail upon:

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